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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,114	07/25/2003	Peter Paul Zilla	P-8794.05 Continuation 2	3869

7590

03/06/2006

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EXAMINER

AMARELD JR, ROBERT W

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/627,114	ZILLA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Robert W. Amareld, Jr.	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 71-87 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 71-87 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Amendment***

The following Office Action contains rejections to previously allowed and/or previously objected-to-as-allowable material as indicated in Office Action mailed 4/7/05. Accordingly, the following action has been made Non-Final.

### ***Priority***

The provisional application 60/144703 (7/20/99), relied on by the parent patent # 6673108 offers no support for an in-growth matrix comprising a concentration gradient of material and therefore priority is not granted to this date. The earliest priority date granted to this application is 11/5/1999 as per the filing date of US Pat# 6554857.

### ***Terminal Disclaimer***

The terminal disclaimer filed on 7/11/05 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Pat # 6554857 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

Art Unit: 3738

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 71-83, 85-87 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 6673108. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between the application claims and the patent claims lies in the fact that the patent claims include more elements and are thus much more specific. Thus the invention of the patent claims are in effect a "species" of the "generic" invention of the application claims. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since the application claims are broader and anticipate the narrower patent claims, they are not patentably distinct from the patent claims.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 71-84 are rejected under 35 U.S.C. 102(b) as being anticipated by Zaffaroni.

Zaffaroni discloses a material having uniform pore properties across all its dimensions (col. 5, lines 4-42) including continuous and non-continuous pores that may be connected and of **any** various regular shapes or irregular shape (col. 10, lines 40-55), which would include spherical or helical pore configurations where the pores and material are fully capable of being in-growth matrix which comprises a concentration gradient of drug material across the material (col. 15, lines 1-30) where “the term “drug” broadly includes physiologically or pharmacologically active substances for producing a localized or systemic effect” (All of col. 18) and may include any drug including synthetic drugs, steroids (col. 18, lines 54-63) including growth hormone. The drug is encased in a carrier material, which concentration will vary at least by the amount of drug it is carrying and may include inorganic or organic molecules of natural or synthetic origin or both (col. 12, lines 60-68) including hydrogel, collagen (which is a protein and a peptide), polymers and the like (col. 14, lines 1-12). Under Zaffaroni’s definition of a drug, the materials of a delivered gene, fibrin matrix and polyethylene glycol are included within the acceptable materials for the gradient. The pores have a size from about 10 angstroms –100µm, which is within 300µm of one another (Col.10, lines 32-35). Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure.

Claims 71, 72 & 85-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Karwoski (US Pat# 4718907). Karwoski discloses a scaffold with uniformly shaped pores (Figure 1) which is an in-growth matrix comprising a concentration gradient of fluorine to carbon (col. 2, lines 15-50). The device is disclosed as a tubular vascular prostheses, which is a vascular graft and is fully capable of being a sewing ring or synthetic heart valve.

### ***Conclusion***

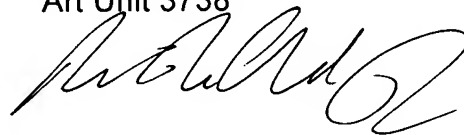
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hoffman, US Pat# 4842575 –vascular graft; Athanasiou, US Pat# 5876452- implant; Berg, US Pat# 6371982- graft.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am -5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert W Amareld, Jr.  
Examiner  
Art Unit 3738



RWA



**CORRINE McDERMOTT**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 3700**